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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,123	02/03/2004	Corinna Sundermann	029310.53175US	7253

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EXAMINER

AULAKH, CHARANJIT

ART UNIT PAPER NUMBER

1625

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/770,123		SUNDERMANN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Charanjit S. Aulakh		1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2 pages</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. According to paper filed on Jan. 30, 2006, the applicants have amended claims 1, 27, 36, 37 and 40.
2. Claims 1-52 are pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on Jan. 30, 2006 have been fully considered but they are not persuasive regarding enablement, some indefiniteness and some prior art rejections. In regard to enablement rejection, the examiner does not agree with the applicants arguments that the specification is enabling for treating all conditions mentioned in the instant claims 50-52 and alleviating pain. The applicants mention several references in the literature which discloses the relationship between the given indications and the glycine binding site of the NMDA receptor. This is not convincing. The compounds of these references are not closely related in structure to the instant compounds and furthermore, it is not clear whether therapeutic effect is indeed due to an antagonistic effect or an agonistic effect at glycine binding site of the NMDA receptor. The applicants need to provide references showing either well known utility of compounds related very closely in structure to the instant compounds or their efficacy in known animal models of specific disease conditions. As stated clearly in the last office action, NMDA receptor antagonism is only one of the several other known mechanisms responsible for the etiology of pain and therefore, the instant compounds will have utility in only treating pain. In regard to indefiniteness rejections, the examiner does not agree

with the applicants arguments regarding definiteness of the terms, alleviating and inhibiting in instant claims 47, 51 and 52.

In regard to prior art rejections over Borrione and two Kobayashi's references, the applicants have amended claims to salts of compounds to overcome these rejections. However, preparing salts of known compounds is within the routine skill of an artisan and furthermore, is not a patentable subject matter. The instant claims 1-24 are now rejected under 35 U.S.C. 103(a) since it would have been obvious to one skilled in the art to prepare salts of known compounds disclosed in these three references.

In regard to prior art rejection over Gerlach's reference, the examiner does not agree with the applicants arguments that this reference is not available under 35 U.S.C.

102(e). The filing date of Gerlach's reference is Aug. 7, 2002 whereas the filing date of instant application is Feb. 3, 2004. The applicants argue that PCT/EP01/00588, filed on Jan. 19, 2001 is not published in English and therefore, the filing date of Gerlach's reference is Aug. 7, 2002 instead of Jan. 19, 2001. The same principle applies to the instant application since PCT/EP02/08729 is also not published in English and therefore, the filing date of instant application is Feb. 3, 2004 and not Aug. 5, 2002.

In regard to ODP rejection, the applicants have filed a terminal disclaimer to overcome this rejection.

### ***Conclusion***

4. The rejection of claims 47 and 50-52 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

5. The rejection of claims 47, 51 and 52 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
6. Claims 1-9, 11 and 15-24 are now rejected under 35 U.S.C. 103(a) over Borrione's reference instead of 35 U.S.C. 102(b).
7. Claims 1-24 are now rejected under 35 U.S.C. 103(a) over both Kobayashi's references instead of 35 U.S.C. 102(b) and 102(a).
8. Rejection of claims 1-52 under 35 U.S.C. 102(e) over Gerlach's reference is maintained for the reasons of record.

NEW        GROUNDS    OF    REJECTION

***Claim Rejections - 35 USC § 102***

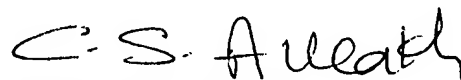
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-52 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Gerlach ( WO 01/58875, cited on applicants form 1449 ).  
  
Gerlach discloses substituted 1,2,3,4-tetrahydroquinolines-2-carboxylic acid derivatives, a process for preparing these compounds, pharmaceutical compositions containing these compounds and methods of treating pain and other disease conditions using these compounds. The exemplified compounds ( see examples 1-4, 6, 12, 59-64, 67 and 76 ) disclosed by Gerlach clearly anticipate the instant claims.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charanjit S. Aulakh  
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Art Unit 1625